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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,441	07/07/2003	Jong Soo Ko	2013P095	7432

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT PAPER NUMBER

1743

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,441

Applicant(s)

KO ET AL

Examiner

Natalia Levkovich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/17/2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 11 recites a microfluidic device ' wherein a sample injected via the first fluid inlet port flows into the sensing chamber through the first fluid addition chamber by capillary force and stops flowing at the sensing chamber having appreciably large outlets, and a buffer solution loaded via the second fluid inlet port is forced to flow

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by the action of an external pump, through the channel and the sensing chamber, for washing reacted products, and is reserved in the used reagent reservoir'.

The claim is narrative in form and replete with indefinite and functional or operational language. The structural features of the elements, providing for the above cited functionality, remain unclear. For example, the claim recites injecting the sample via the first fluid inlet port, which implies the use of an unspecified injecting element (which may be, for example, a pump). Therefore, the sample must be driven not only by capillary force, but also by some external injecting device. On the other hand, the buffer 'driven by an external pump' is inevitably subject to the capillary force. Therefore, the distinction between the structures providing for the two, allegedly different driving mechanisms of driving the sample and the buffer (which Applicant seems to imply), is unclear.

Additionally, the 'external pump' is not positively claimed, and, consequently, is not accorded any patentable weight. Examiner also notes that, in general, inlets are capable of being connected to some external devices, including pumps.

Finally, the term 'appreciably large' [outlets] is relative and , therefore, indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennen et al. (US 6632400) in view of Bjornson et al. (US 6827906).

Brennen discloses an integrated microfluidic device comprising a microfluidic component ['channel substrate' – Ex.] bonded to an electronics component ['sensing substrate' – Ex.] having a "circuit for processing signals related to the microfluidic component" (including pads / electrodes, etc. - see the Abstract).

Brennen teaches that "in a preferred embodiment, the microfluidic component includes a substrate that has features such as microfluidic channels, microfluidic compartments, and microfluidic flow control elements. Therefore, the microfluidic component may include known features such as capillary channels, separation channels, detection channels, valves and pumps" (Col.2, lines 50 plus). However, Brennen does not specifically teach the particular microfluidic layout, as recited in claim one.

Nevertheless, the structures which include multiple inlets connected to several serially arranged chambers, are well known in the art. For example, Bjornson discloses a microfluidic structure (shown in Figure 9) comprising a number of inlets, including inlets 102 and 116 arranged at two different sides of the structure and connected to chamber 135 [sensing chamber' – Ex.], which, in turn, is further connected to reservoir 124 for

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receiving wastes . Chamber 125 ['reaction chamber' – Ex.] is located between the 'sensing chamber' and the unmarked sections of the main channel which can be referred to as 'reaction barrier' and 'time delay'. The inlets appear to be surrounded by chambers which can serve as 'addition chambers'. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed microfluidic structures composed of conventional microfluidic elements in various combinations (including the structure discussed above), in the modified apparatus of Brennen, in order to provide means for achieving various specific sample processing goals.

Referring to claims 13-14, although Brennen does not teach recesses in sensing substrate corresponding to the inlets and/ or to the channel, the reference does teach that the "electrical features may include... direct contacts to the fluid"(Col.3, lines 5 plus). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged recesses located over corresponding fluidic elements (ports or channels) in the modified apparatus of Brennen, in order to better accommodate electrical elements needed for controlling the fluid flow.

With respect to claims 15-18, Brennen does not teach hydrophilic / hydrophobic materials of different degree of hydrophilicity / hydrophobicity , and their combinations. However, such materials are routinely used in the art, specifically, in microfluidic circuits, for controlling and directing the fluid flow. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed hydrophilic

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/ hydrophobic materials in the modified apparatus of Brennen, in order to enhance control over the fluid flow.

With respect to claim 19, Brennen teaches electrical heating or cooling elements integrated in or on the microfluidic component in column 3, line 10.

Response to Arguments

7. Applicant's arguments filed on 07/17/2006 have been fully considered but they are moot in view of new grounds of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:


Yang et al.(US 6468761) – discloses microfluidic devices optionally employing both external pumps “sealably fitted to the inlet or outlet of the channel” and “capillary forces ... used to provide fluid pressure for continuous fluid flow of materials...” (Col.17, lines 30-60).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700